COMPLIANT FOR MEDICARE

Does It Exist? Is It Scalable?
Please Complete Your Evaluation
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Speakers

- Zeeshan Hayat
  CEO, Prizm Media

- Karina Hayat
  President, Prizm Media

- Rachel Hirsch
  Senior Associate, Ifrah Law
Query: How can compliant marketing produce scalable lead generation opportunities for your business while improving your approach to senior selling?
# Housekeeping Checklist for Compliant Lead Generation

<table>
<thead>
<tr>
<th>Business/Operations</th>
<th>Your Lead Generation Co.</th>
</tr>
</thead>
<tbody>
<tr>
<td>_____ Trained Sales Team</td>
<td>_____ Track Record</td>
</tr>
<tr>
<td>_____ Lead Management Software</td>
<td>_____ Lead Management Software</td>
</tr>
<tr>
<td>_____ Dialer System (inbound/Outbound)</td>
<td>_____ Compliance Team</td>
</tr>
<tr>
<td>_____ Sales Tracking System/Analytics</td>
<td>_____ Best Practices (TCPA, HIPPA, Medicare, OIG)</td>
</tr>
<tr>
<td>_____ Processing Team</td>
<td>_____ QA Team</td>
</tr>
<tr>
<td>_____ ROI (Rate of Investment)</td>
<td>_____ Access to Ads/Recordings</td>
</tr>
<tr>
<td>_____ LVC (Lifetime Value per Customer)</td>
<td>_____ Agreement with defined yearly budget</td>
</tr>
<tr>
<td>_____ Marketing Budget (6+ mos)</td>
<td>_____ Reporting/Analytics</td>
</tr>
</tbody>
</table>

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WHAT IS RESPONSIBLE MARKETING vs. Traditional Media
HOW It Works?

Engage Consumer

Consumer INITIATES Response

Consent

Lead Generation

Direct
Direct Mail
Email
Telephone

Advertising
Print
Digital
E-Marketing
Website

PR
Press Releases
Articles

Social Media
Blogs
Network Sites

Events
Trade Shows
Conferences
Webinars

Television

(with consent)
WHY Is It Important?

ACCELERATES

How Many Leads?

Sales Cycles

How Many Sales Reps?

Growth

Desired ROI

profitability
HOW TO SCALE

DME: Logistics & Operations Matter
Lead Generation is a Partnership

50/50

✓ Trained & Efficient Sales Team
✓ Trained & Efficient Processing Team
✓ Telephone System
✓ CRM
✓ Tracking/Analytics (Measure ROI)
✓ Knowing LVC (Lifetime Value per Customer)
✓ Min 6 mo Budget
Your Lead Generation Company

- Track Record
- Lead Management System
- Compliance Team
- QA Team
- Reporting/ Analytics
- Aligned w/ your sales process
- BEST PRACTICES
BEST Practices

✓ TCPA Compliance/Non-solicitation

✓ Wireless/Landline Scrub (web and phone – not inbound)

✓ Record keeping (Consent, recordings, ads...)

✓ Confidentiality/Security

✓ Marketing Compliance (Disclosure of Product/Service)

✓ Master Services Agreement w/ defined yearly budget
Industry Requirements

✓ Telephone Consumer Protection
✓ Express consent
✓ Disclosure of product service
✓ No obligation

Clear line of Sight
Non-Solicitation
Industry Requirements: TCPA

Telephone Consumer Protection Act
(47 U.S.C. § 227)

- Restricts telephone solicitations (i.e., telemarketing) and the use of automated telephone equipment, such as automatic dialing systems, artificial or prerecorded voice messages, SMS text messages, and fax machines.
Industry Requirements: TCPA

Mobile

2013 RULE CHANGE: Marketers Must Receive Prior Express Written Consent From Consumers Before Placing Autodialed Calls/Texts Or Generating Pre-Recorded Messages To Cell Phones For Telemarketing Purposes.

EXCEPTIONS:

• Live (Non-Autodialer) Telemarketing Calls To Wireless Numbers Do Not Require Consent

• Live (Non-Autodialer) Informational Calls To Wireless Numbers Do Not Require Consent

Landline

2013 RULE CHANGE: Marketers Must Obtain Prior Express Written Consent Before Generating Pre-Recorded Telemarketing Messages to Consumers’ Landlines.

EXCEPTIONS:

• Live Telemarketing (With Or Without Autodialer) Calls To Residential Lines Generally Do Not Require Consent

• Live Informational Calls (With Or Without Autodialer) To Residential Lines Do Not Require Consent
Industry Requirements: TCPA

What Is Consent?

• Must Be Unambiguous – i.e. “Clear and Conspicuous Disclosure”
• May Not Be A Condition of Purchase
• Requires Consumer to Designate a Phone Number

How Is It Obtained?

May Be Obtained Via:

• Website Form;
• Email;
• Text Message;
• Telephone Key-Press; or Voice Recording

REMEMBER!
• Companies Should Scrub DNC List
• Consumer Can Revoke Consent

Who Bears The Burden Of Proof? Seller/Supplier Bears Burden of Compliance
Where Things Get Complicated?

1. Create Interest
2. Obtain Consent
3. Contact
4. Qualify

Referral

IE. TV or web inquiry

Raw Lead
Legal Requirements – Healthcare-Related Statutes

- Medicare Anti-kickback Statute (42 U.S.C. §1320a-7b)
- Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a (a))
- Anti-Solicitation Statute (42 U.S.C. § 1395m(a)(17))
- False Claims Act (31 U.S.C. § 3729)
- False, Fictitious or Fraudulent Claims (18 U.S.C. § 287)
- Stark II Statute (42 U.S.C. § 1395nn)
Legal Requirements

Medicare/Medicaid Anti-Kickback Statute (42 U.S.C. §1320a-7b)

- It is a felony for a person or entity to knowingly or willfully solicit or receive any remuneration in return for referring an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or in return for purchasing, leasing or arranging for or recommending the purchasing or leasing of any item for which payment may be made under federal health care programs.

- It is a felony for a person or entity to knowingly or willfully offer or pay any remuneration to induce a person to refer a person for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

- **NOTE:** Violation is Presumed, UNLESS a “Safe Harbor” Exception Applies.
Is Anti-Kickback Statute Implicated?

- Anti-Kickback Statute Makes It a Crime For Company A (DME/HME Supplier) To Give Anything Of Value (e.g., money) To Company B (Lead Generation Company) In Exchange For Company B:
  
  - Referring Patients Covered By Government Health Care Program;
  
  - Arranging For the Referral Of Government Program Patients; or
  
  - Recommending Purchase Of Product That Is Reimbursed By A Government Health Care Program.

**KEY DISTINCTIONS:**

“Purchase a Lead” = Acceptable

“Pay for a Referral” = Violation
OIG Special Fraud Alerts And Special Advisory Bulletins

- Discuss Business Arrangements That OIG Believes May Be Abusive.
- Educate Health Care Providers Concerning Fraudulent Or Abusive Practices.
- Reflect OIG’s Opinions Regarding Application Of Fraud And Abuse Laws.
- Provide Clarity Regarding Certain Business Arrangements.
OIG Advisory Opinion 08-19
Case Study

- Distinguished Between “Raw/Unqualified Leads” v. “Qualified Leads”

- Determined Not To Seek Enforcement Action Against Parties For The Particular Arrangement At Issue.

- Considered The Following Factors In Reaching Its Determination:
  - No Collection Of “Health Information” By Advertiser.
  - Arrangement Passively Routed Calls/Emails Initiated By Lead.
  - No Active Steering of Patients To Particular Provider.
Raw/Unqualified V. Qualified Leads

- “Raw/UnQualified Lead” – LGC Only Collects Name, Address, And Phone Number of Medicare Beneficiary.

- “Qualified Lead” – LGC Collects Additional Information About Beneficiary – e.g., physician’s name, Medicare number, illness/diagnosis, products beneficiary is currently using….
“Unqualified” v. “Qualified” Leads – Non-Offending Arrangements


• “Qualified Leads” – Arrangement Must Meet Requirements Of The Personal Services and Management Contracts Safe Harbor To Anti-Kickback Statute:
  o Fixed One Year in Advanced (e.g., $100,000 over next 12 months).
  o Compensation Must Be Fair Market Value Equivalent of LGC’s services.
  o Compensation Cannot Take Into Account Volume of Referrals Generated by LGC.
You’ve Purchased A Lead, Now What?

Telephone Solicitation Statute/Supplier Standard 11

• Arrangement must be examined within context of 42 U.S.C. §1395m(a)(17) – “Medicare anti-solicitation statute” – Prohibits DME company from contacting a Medicare beneficiary by telephone concerning furnishing of covered item of DME unless:

✓ Beneficiary has given “written permission” for contact;

✓ DME company is contacting beneficiary only about an item company has already provided to beneficiary; or

✓ DME company has provided at least one covered item to beneficiary during 15 months preceding the contact.
What Constitutes “Written Permission” Under Anti-Solicitation Statute

- Checking a check box showing clear consent to be called (not just contacted) by supplier
- Electronic Signature suffices
- [Note Similarities Between Anti-Solicitation Statute and TCPA]

**BUT:** Anti-Solicitation Statute Unlikely Violated *If* Prospective Customer Calls Toll-Free Number and Verbally Requests that Supplier Return the Call.

As in the process of Raw TELEVISION Generated Leads
2010 OIG Updated Special Fraud Alert:

“Telemarketing by Durable Medical Equipment Suppliers”

• “A physician’s preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary.”

• Response to OIG Alert – CMS Issued “Telemarketing Frequently Asked Questions”

• Clarified that: “If a physician contacts a supplier on behalf of a beneficiary with the beneficiary’s knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact would not be considered ‘unsolicited.’”
And Don’t Forget About HIPAA

Supplier Is Also Subject To Requirements Of HIPAA, Which Prohibits The Use Or Disclosure Protected Health Information (“PHI”) Not Specifically Permitted Or Required By HIPAA.

• PHI: Includes information that is created or Received by a health care provider that:

  • Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and:
  • (i) That identifies the individual; or
  • (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual (45 C.F.R. § 164.103).

• Definition encompasses identification and contact information for a lead, as well as information that relates to the lead’s interest in DME/HME.
Recent Enforcement/Prosecutorial Efforts
Recommendations For DMEs Purchasing Leads:

- Conduct Due Diligence Of Your LGCs. Use Housekeeping checklist
- Obtain Requisite BAA Before Disclosing PHI.
- Audit LGCs Call Logs and Advertisements.
- Develop Comprehensive Compliance Plan.
- Include Indemnification Rights in Your Contracts.
Questions?

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blog: www.PrizmMedia.com/blog

Thank you!